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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,997	08/01/2003	Peiyuan Wang	09797.0002-00	8974
22852	7590	05/11/2011		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER PACKARD, BENJAMIN J	
			ART UNIT	PAPER NUMBER
			1612	
			MAIL DATE	DELIVERY MODE
			05/11/2011 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/632,997

## Applicant(s)

WANG ET AL.

## Examiner

BENJAMIN PACKARD

## Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 19, 25, 26, 28, 29, 31 and 33-37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 18, 21-24, 27, 30 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 02/01/11, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 18, 21-22, 27, 30, and 32** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al (J. Org. Chem., 1976, 41 (7), 1100-1104) in view of Patani et al (Chem. Rev. 1996, 96, 3147-3176).

Applicants assert Examiner has failed to meet the burden required by law for two reasons. First, Applicants assert Examiner has not shown that compound 4 of Sasaki would have been considered a suitable "lead compound" because Applicants assert Sasaki explicitly states compound 4 could be reconverted to 33a and that Sasaki teaches 4 mechanisms for synthesizing compound 3a, only 1 of which yields compound 4 the disclosed synthesis is ambiguous. Second, Applicants assert the cited references fail to suggest the modification advanced by the Examiner where Patani's results show that substitutions can result in unpredictable effects, e.g. result in lower biological activity.

Examiner disagrees. First, Sasaki et al explicitly discloses compound 4, and as such, suggests it is a 5-bromopyrimidine derivative of interest. While there are multiple formulations for compound 3a, such disclosure does not teach away from the fact that compound 3a and compound 4 appear to be the end products of the various synthesis routes. Further, the reference notes that compound 4 was tested for UV absorption among other tests. While the reference does disclose compound 4 may be reconverted to compound 3a, such a disclosure does not teach away from the disclosure of compound 4.

With regards to a "lead" compound, while Examiner disagrees with the narrow interpretation of Takeda as suggested by Applicants that there must be a single compound for further development, Examiner notes that even were compound 3a to be considered the "lead" compound, compound 4 is simply the deprotected analogue of 3a (pg 1101, right column, first full ¶). Thus, after formulating 3a, the unprotected form would be compound 4 which the skilled artisan would consider an obvious variant of 3a. As such, the skilled artisan would be motivated to select either compound for additional testing, with the selection depending on whether the compound requires protection. This fact situation differs from a compound which is solely disclosed as an intermediate product in that compound 4 is in fact an end product of the disclosed synthesis..

Second, while the various results of Patani do show varied biological activity results, Examiner notes that the modified compounds still retain biological activity. As such, Patani et al suggest the formation of bioisomers can result in safer and more clinically effective agents (pg 3147, first paragraph). Thus, the skilled artisan would

expect that some may have lower efficacy, but may result in increased safety. The prior art need not disclose the specific synthesis of the elected species, given such a disclosure would be basis for an anticipatory rejection, not an obviousness rejection.

**Claims 23 and 24** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al (J. Org. Chem., 1976, 41 (7), 1100-1104) in view of Patani et al (Chem. Rev. 1996, 96, 3147-3176), the combination further in view of Gilbert et al. (Antimicrobial Agents and Chemotherapy, 1986, Vol. 30, No. 2, pp. 201-205).

Applicants assert Gilbert is relied upon solely for the inclusion of an antiviral agent and does not remedy the deficiencies of Sadaki and Patani, and the rejection should therefore be withdrawn.

Examiner disagrees. Sadaki and Patani are discussed above and as no deficiencies are found, the instant rejection is maintained.

#### ***Allowed Subject Matter***

**Claim 20** is allowed for the reasons of record.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN PACKARD whose telephone number is (571)270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/  
Examiner, Art Unit 1612

Application/Control Number: 10/632,997  
Art Unit: 1612

Page 6

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612